

Attorney's Docket No.:06618-045002

REMARKS

These remarks are in response to the Final Office Action mailed January 30, 2003, the Advisory Action mailed April 29, 2003, the Advisory Action mailed June 9, 2003, and the Advisory Action mailed October 29, 2003. Claims 2, 5, 6 and 8 are allowable. Claims 1, 4, 14 and 15 have been amended. Support for the amended claims can be found throughout the specification. Specifically, support for the recitation of "further cross-linking the silyl lipids to an encapsulating material or matrix" as set forth in claim 1, part d), can be found at page 3, lines 31-36 and at page 4, lines 34-36, bridging to page 5, lines 1-2. Additional support can be found in Figures 6A and 6B. No new matter has been added. Claims 1, 2, 4-6, 8, 9 and 12-17 are pending and at issue. Applicants request reconsideration of the present application.

I. REJECTIONS UNDER 35 U.S.C. §112, SECOND PARAGRAPH

Claim 4 stands rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite for the recitation of "formed elements." Specifically, the Office Action alleges that the recited term is not art recognized. Applicants traverse this rejection as applied to amended claim 4.

Claim 4 has been amended to recite, in part, modifying the pH of "a patients blood during renal dialysis" by contacting the subjects blood with a lipid membrane prepared by the method claim 2. Applicants note that the present invention provides an improved means for stabilizing the pH of a patients blood during dialysis (see Example 8, Page 10). The specification clearly intended to convey to the skilled artisan that the sol-gel encapsulated phospholipid vesicles of the present invention can be used to filter blood during dialysis.

In view of the above discussion, Applicants request that the rejection under 35 U.S.C. §112, second paragraph be withdrawn.

II. REJECTIONS UNDER 35 U.S.C. §112, FIRST PARAGRAPH

*Written Description*

Claims 4 and 9-17 stand rejected under 35 U.S.C. §112, first paragraph, as allegedly containing subject matter not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention. Applicants respectfully traverse this rejection.

Specifically, the Office Action that the recitation of "membrane is associated with an acidic compound capable of modifying the pH of the fluid" in claim 4, and "stabilizing the lipid membrane" in claim 9, presents new matter because they were not present in the specification as filed.

With regard to the recitation of a lipid membrane "associated with an acidic compound capable of modifying the pH of the fluid," Applicants point to page 10, lines 7-17, which state:

Current methods for dialysis employ systems wherein ammonia is transported across a dialysis membrane and is trapped by an acidic compound such as citric acid. Disadvantages of currently used dialysis membranes include short shelf life and instability during usage. The sol-gel encapsulated phospholipid vesicles of the present invention may be used in dialysis membranes, thus affording a more stable and efficient dialysis system than the currently used citric acid-based membrane. Ammonia exchange was quantitated by passing a solution of ammonium phosphate through the sol-gel encapsulated vesicle membrane and determining the output pH value (emphasis added).

The passage clearly supports Applicants contention that they were in possession of a method for modifying the pH of a fluid using a lipid membrane "associated with an acidic compound" at the time the application was filed.

With regard to the recitation of "stabilizing the lipid membrane," Applicants point to page 4, lines 28-34, of the specification, which state:

The silyl lipid functions not only as a component lipid molecule to form a bilayer or multilayer structure in the LB membrane or vesicle, but also as a cross-linking seed such that condensation of the silanol head with the silyl lipid results in the formation of a fine mesh at the surface of the lipid membrane or vesicle, thus **enhancing the stability** of the membrane or vesicle (emphasis added).

This passage clearly supports Applicants contention that they were in possession of a method for enhancing the stability of a lipid membrane at the time the application was filed.

Support for the recitation of "further cross-linking the silyl lipids to an encapsulating material or matrix" as set forth in claim 1, part d), can be found at page 3, lines 31-36, which recites:

"[I]n the present invention, the silyl lipids are cross-linked via hydrolysis and condensation with the silanol groups or heads at the surface of the vesicles of LB membranes, and with the encapsulating hybrid mixture sol-gel matrix."

and at page 4, lines 34-36, bridging to page 5, lines 1-2, which recites:

"Furthermore, silyl lipids may co-condense with the silanol groups at the surface of the **encapsulating material or matrix (sol-gel, hybrid mixture sol-gel or glass)** (emphasis added), thus

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covalently bonding with the matrix and improving its stability."

Additional support for the recitation of "encapsulating material or matrix" can be found in Figures 6A and 6B. Thus, the specification clearly supports Applicants contention that they were in possession of a method for cross-linking silyl lipids to an encapsulating material or matrix at the time the application was filed.

Accordingly, Applicants request that these rejections under 35 U.S.C. §112, first paragraph, be withdrawn.

### III. REJECTIONS UNDER 35 U.S.C. §102

Claims 1 and 13-16 stand rejected under 35 U.S.C. §102(b) as allegedly anticipated by Nakamura. Applicants traverse this rejection as they may apply to amended claim 1.

Claim 1 has been amended to recite, in part, "further cross-linking the silyl lipids to an encapsulating material or matrix." Support for the limitation is discussed above. Applicants submit that the cited reference fails to teach cross-linking to an encapsulating material or matrix and therefore fails to teach each element of amended claim 1. Accordingly, Applicants respectfully request that the rejection under 35 U.S.C. §102(b) be withdrawn.

In summary, for the reasons set forth herein, Applicants maintain that claims 1, 2, 4-6, 8, 9 and 12-17 clearly and patentably define the invention. Applicants further request that the Examiner reconsider the various grounds set forth in the Office Action and Advisory Actions and allow the claims which are now pending.

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If the Examiner would like to discuss any of the issues raised in the Office Action, Applicants' representative can be reached at (858) 678-5070. Please charge any fees, or make any credits, to Deposit Account No. 06-1050.

Respectfully submitted,

Date:

11/14/03



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